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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,214	04/17/2006	George Gorodeski	29519/040044	7011

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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01/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@calfee.com
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Office Action Summary	Application No. 10/576,214	Applicant(s) GORODESKI, GEORGE	
	Examiner ELIZABETH R. MACNEILL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/11/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7, 12, 14, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al (US 6,139,538).

Houghton teaches a drug delivery member (Fig 1) comprising a medication impermeable barrier (102) and a medication carrying matrix (126) adapted to adhere (via conforming) to internal human tissue (cervix) and release (by iontophoresis) the medication to the human tissue. See rim 104; cap portion 130; retainer 178; applicator 187/180

3. Claims 1, 3, 4, 11, 12, 14-16, 27-30, 36, and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by Tracy et al (US 6,526,980).

Tracy teaches a drug delivery member (Fig 1) comprising a medication impermeable barrier (104) and a medication carrying matrix (112, 602) adapted to adhere (fingers 802 or rim 1002, or inflatable ring 1102) to internal human tissue (cervix) and release (by dissolution) the medication to the human tissue. As to claim 36, Fig 9 shows ribs and Fig 7 shows a tubular member (104) with a second opening (710).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8, 9, 17, 21, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton as applied to claims above, and further in view of Brodman et al (US 5,002,540).

Houghton does not teach the delivery of 5-fluorouracil to the cervix. Houghton teaches delivery of a generic drug through his reservoir (126). Brodman teaches the delivery of 5-fluorouracil to the cervix (Col 4 line 20) to treat cancer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the drug of Brodman with the delivery device of Houghton to treat cervical cancer.

6. Claims 8, 9, 17, 21, 22, 34, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tracy as applied to claims above, and further in view of Brodman et al (US 5,002,540).

Tracy does not teach the delivery of 5-fluorouracil to the cervix. Tracy teaches delivery of a generic drug through his reservoir (602). Brodman teaches the delivery of 5-fluorouracil to the cervix (Col 4 line 20) to treat cancer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the drug of Brodman with the delivery device of Tracy to treat cervical cancer.

7. Claims 10, 35, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tracy as applied to claims above, and further in view of Weiner et al (US 5,466,233).

Tracy does not teach that this matrix is made of a carboxy polymer. Weiner teaches a drug delivery reservoir (Fig 1) with a carboxy polymer carrier (Col 11 line 12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a carrier as taught by Weiner to stabilize the reservoir.

8. Claims 13 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tracy as applied to claims above, and further in view of Zaffaroni (US 3,898,986).

Tracy does not teach that the barrier dissolves in the body. Zaffaroni teaches an intrauterine device that degrades after being placed in the body (Abstract and Col 6 line 8). As to claim 40, Tracy does not teach the use of pectin as the biotransformable material. Zaffaroni teaches that pectin may be used for the material (Col 7 line 39). The choice of an alternate material is within the skill of an ordinary worker in the art as a matter of obvious design choice.

9. Claims 2,5-7, 18-20, 24-26, and 31-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Tracy as applied to claims above, and further in view of Houghton.

Tracy does not teach an annular rim or projection on the cervical cap. Houghton teaches rim (104) and cap/projection (130). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the rim and cap of Houghton to center the device over the cervix and prevent medicine from leaking out of the device.

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tracy. Tracy does not teach that the ribs are made of nitinol. Tracy teaches a shape memory plastic. The choice of an alternate material is within the skill of an ordinary worker in the art as a matter of obvious design choice.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/

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Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767